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10/561,074	05/22/2006	Le Yi Wang	RM.WSL	1880

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EXAMINER	
SYED, ATIA K	

ART UNIT	PAPER NUMBER
3769	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,074	WANG ET AL.	
	Examiner	Art Unit	
	ATIA SYED	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 June 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges Applicant's response filed on November 20, 2009.

Response to Arguments

Applicant's arguments with respect to claims 1, 4 and 7 filed on June 8, 2009 have been considered but they are not persuasive. Applicant has argued three points: i) 35 U.S.C. 101 rejections of claims 1, 4 and 7; ii) 35 U.S.C. 112 rejection of claim 7; and iii) 35 U.S.C. 102 under Kangas et al.

Regarding Applicant's first argument, Examiner disagrees that claims 1, 4 and 7 recite patentable subject matter. Claims 1-6 are rejected under 35 U.S.C. 101 for not being significantly tied to another statutory class and lack of utility. Similarly claims 7-10 are rejected for failing to comply with the utility requirement of 35 U.S.C. 101. For detailed explanation see 35 U.S.C. 101 rejections below.

Regarding Applicant's second argument, Examiner agrees with attorney's assertion that the signal combiner arrangement, the limiter and the virtual anesthesia monitor are data structures implemented by a computer (Remarks, page 7). However, claim 7 as currently presented does not recite a computer. Therefore the meters and bounds of claim 7 can not be discerned. For detailed explanation see 35 U.S.C. 112 rejections below.

Regarding Applicant's third argument, Examiner has cited additional sections of Kangas et al. to further clarify the rejection. See Examiner's note on claim interpretation and 35 U.S.C. 102 for details.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In particular, claims 1-6 are drawn to a process. Under 35 U.S.C. §101 a process must 1) be tied to another statutory class (such as a particular apparatus) or 2) transform underlying subject matter (such as an article or materials) to a different state or thing. This is called the **"machine-or-transformation test"**.

There are two corollaries to the machine-or-transformation test. First, a mere field-of-use limitation is generally insufficient to render an otherwise ineligible method claim paten-eligible. This means the machine or transformation must impose meaningful limits on the method claim's scope to pass the test. Second, insignificant extra-solution activity will not transform an unpatentable principle into a patentable process. This means reciting a specific machine or a particular transformation of a specific article in an insignificant step, such as data gathering or outputting, is not sufficient to pass the test.

In this case claim 1 recite a method of assisting a human expert in reducing predictable variations in the depth of anesthesia by solving a mathematical formula using a computing device having a memory. However, use of a computing device to solve a formula does not impose meaningful limits on the scope of method claim. Furthermore, the use of a computing device to solve an equation/formula is merely an insignificant extra-solution activity i.e. the method can be performed without the use of a computing device such as on a piece of paper by

using ones hands and mind. Thus, the tie between the method of claim 1 and the computing device recited in claim 1 is neither meaningful nor significant. Claim 1, therefore does not pass the machine-or-transformation test. Furthermore, claims 2-3 are rejected for at least being dependent on rejected claim 1.

Claims 4-6 are rejected for substantially the same reasons as claim 1.

(For details visit: http://ptoweb.uspto.gov/patents/3700/documents/101.memo.01.07.09.pdf)

35 U.S.C. 101 further requires a process to be useful. Accordingly, one must then consider whether the claimed invention produces a useful, concrete, **and** tangible result.

(1) Useful Result

For an invention to be "useful" it must satisfy the utility requirement of section 101. The USPTO's official interpretation of the utility requirement provides that the utility of the invention has to be (i) specific, (ii) substantial and (iii) credible. See MPEP 2107. It can be argued that the claim does not provide a useful result such that the claim does not actually solve a problem. The method of claim 1 recites only one step i.e. "the step of solving in the computing machine the formula". A method comprising the step of solving a formula with no implication and or output of result thereafter does not appear to be useful.

Similarly the method of claim 4 does not have an output i.e. after the sensitivity of patient is determined, how is it then used? The method does not appear to be useful since there is no step of displaying and/or announcing the result to the user.

(2) Tangible Result

The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a 101 judicial exception, in that the process claim must set forth a practical application of that 101 judicial exception to produce a real world result.

Regarding the tangible result requirement, the claims 1 and 4 clearly do not provide a practical application for reasons similar to that discussed above. For example, once the formula is solved, how is this result then applied? And/or how does solving a formula leads to reducing predictable variations in the depth of anesthesia?

(3) Concrete Result

Another consideration is whether the invention produces a "concrete" result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Resolving this question is dependent on the level of skill in the art. For example, if the claimed invention is for a process which requires a particular skill, to determine whether the process is substantially repeatable will necessarily require a determination of the level of skill of the ordinary skilled artisan.

Regarding the concrete result requirement, claims 1 and 4 do not provide i.e. announce or display results. Furthermore, the process of claims 2 and 4 depend on the skill level of a human expert, provided that different human experts can have different level of skill sets, there is a

reasonable doubt that the result is substantially repeatable and the process can substantially produce the same results again.

In view of the above analysis, Applicant's claims 1and 4 are processes which includes a judicial exception therein. Upon review of the claims as a whole, there is no transformation nor do the claims produce useful, concrete, and tangible results. Accordingly, the claims are non-statutory under 35 U.S.C. 101 and lacks utility.

Furthermore, claims 2-6 are rejected for at least being dependent on rejected claims 1 and 4.

The apparatus of claims 7-10 lacks utility under 35 U.S.C. 101 for the same reasons as identified above. More specifically, the apparatus of claim 7 only performs data processing on stored data and produces a result (virtual anesthesia monitor produces an anesthesia value; claim 7, line 16), however this result is never displayed or announced to the user such that it is not useful. Claim 7 recites an apparatus comprising plurality of virtual instruments (VIs) such as first, second and third memories, signal combiner, limiter and virtual anesthesia monitor used for storing and processing data, however the apparatus does not comprise an output and/or a display such that there is no indication and/or announcement of this result to the user. Claim 7, therefore lacks utility under 35 U.S.C. 101.

Claims 8-10 are rejected for at least being depended on rejected claim 7.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above (lack of utility under 35 U.S.C. 101), one skilled in the art clearly would not know how to make or use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a method of assisting a human expert in reducing predictable variations in the depth of anesthesia. However, the above identified method only comprises one step i.e. solving a formula. It is unclear to the Examiner that how does a single step of solving the formula leads to assisting a human expert in reducing predictable variations in the depth of anesthesia? i.e. what additional steps are performed after solving said formula? More particularly how the output of the formula is used in assisting the human expert? Furthermore, it is unclear to the Examiner what is the output of said formula i.e. the variables y or $f_p(x)$ are not defined in claim 1. Similarly, x, Φ_1, Φ_2 and Φ_3 are undefined, such that the metes and the bounds of the claim can not be discerned.

Furthermore, time periods τ_p and T_p lack antecedent basis i.e. claim 1 defines τ_p and T_p however, it is unclear to the Examiner how τ_p and T_p are being used in the method of assisting a human expert in reducing predictable variations in the depth of anesthesia. It is further unclear to the Examiner what is meant by the limitation "where the coefficients C_1, C_2, C_3, as well as the time periods τ_p and T_p are initiated" (claim 1, lines 6-7). For example if coefficients C_1, C_2, C_3, are constants and τ_p and T_p represent time i.e. real numbers than how are they "initiated"?

Regarding claim 2, it is unclear to the Examiner that the value of 1-10, assigned by the human Expert corresponds to which variable of the formula identified in claim 1. More particularly, how is the value of patient's response to infusion of the anesthesia drug being used to assist a human expert in reducing predictable variations in the depth of anesthesia?

Regarding claim 3, "approximately" is a relative term, use of relative terms renders a claim indefinite such that it is not clear that what is the broadest reasonable interpretation of the claim.

Regarding claim 4, there are two steps identified as the "first step" and two steps identified as the "second step". It is unclear to the Examiner, what is the sequence of the different steps being performed in the method and/or if the two steps identified as "first" and the two steps identified as "second" are being performed simultaneously. Furthermore, the preamble of claim 4 recites a method of determining a "model" corresponding to predicted "patient response" to anesthesia drug delivery. However, the claim fails to recite that how said model is determined by the different steps performed in the method. More particularly, it is unclear to the Examiner that how the steps of determining and entering an initial time delay, a time constant and determining a "nonlinear static function" representing the "sensitivity" of the patient to a

dosage of anesthesia drug, leads to determining a "model" for predicting "patient response" to anesthesia drug delivery. Applicant is advised to use consistent claim language i.e. if a "nonlinear static function" representing the "sensitivity" of the patient is intended to be a "model" for predicting "patient response", than the claim should be amended to recite as such.

Claims 5-6 are rejected for at least being depended on rejected claim 4.

Regarding claim 7, "the system" (claim 7, line 2) lacks antecedent basis. Furthermore, it is unclear to the Examiner that what is the structure associated with the claimed apparatus and/or system. The apparatus as recited in claim 7 comprises first, second and third memories, signal combiner arrangement, limiter and a virtual anesthesia monitor. It is evident from the figures (figs. 1, 11, 14, 15), corresponding description in the specification, and Applicants disclosure on the record (Remarks, page 7) that the signal combiner arrangement, limiter and the anesthesia monitor are virtual instruments (VIs) assembled in a programming language such as LabView™ or C++ i.e. they are data structures or algorithms implemented by a processor (Remarks; page 7, lines 11-16). However, claim 7 as currently presented does not recite a computer or a processor. It is unclear to the Examiner that whether the apparatus of claim 7 is a processor or a memory device (computer readable medium) such as flash drive, floppy disk, CD or any other tangible computer readable media. For example the apparatus of claim 7 can be a processor with above identified data structures embedded in it, on the other hand it can simply be a memory device storing a program i.e. computer readable instructions for the execution of above identified data structures. Claim 7, therefore is indefinite such that the metes and bounds of claim 7 can not be discerned.

Regarding claim 8, the limitation "third anesthesia level" (claim 8, line 1-2), lacks antecedent basis. Claim 7 identifies a "third output signal" (claim 7, line 11) and a corresponding "anesthesia effect level". Applicant is advised to use consistent claim language i.e. if a "third output signal" (claim 7, line 11), is intended to be the "third anesthesia level" (claim 8, lines 1-2), than the claim should be amended to recite as such.

Furthermore, claims 8 and 9 recite the abbreviation "BIS". However there is insufficient antecedent basis for this limitation in the claims. The metes and bounds of the claims cannot be determined because it is unclear to the examiner whether BIS stands for Bispectral index or something different. Examiner suggests amending claim 8 to recite the actual term/phrase rather than the abbreviation.

Claim 10, as currently presented recites "a source of **known unpredictable** disturbances". Examiner suggests amending it to "a source for producing known noise to compensate for unpredictable disturbance signals".

Claims 8-10 are also rejected for being dependent on rejected claim 7.

Note to Applicant Regarding Claim Interpretation

The metes and bounds of claims 1-10 can not be determined due to the highly indefinite nature of the claims as explained above. For examination purposes the claims will be interpreted as follows:

claims 1-6 are interpreted as computer-aided method of predicting the depth of anesthesia, wherein the computer at least has a memory; and

claims 7-10 are interpreted as an apparatus for predicting patient's response to anesthesia i.e. anesthesia depth in a patient relative to administered drug, wherein the apparatus at least comprises a memory.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kangas et al., (US 5,775,330) herein after referred as Kangas.

Regarding claims 1-6, Kangas disclose a method of predicting the anesthetic depth of a patient by performing a bispectral analysis of patient's EEG signals using a back-propagation artificial neural network (column 5, line 4 - column 6, line 48). Furthermore, the hidden layers of artificial neural network are (ANN) trained and reconfigured to chose variables for minimizing mean square error (MSE; read on Weiner structure) and back-propagate data sets to recognize nonlinearities (reads over Hammerstein structure; column 6, lines 9-48). See "Example 1" for detailed information of data acquisition, processing, and calculation of result i.e. depth of anesthesia.

Regarding claims 7-10, Kangas disclose a portable device comprising electrodes for data acquisition (EEG signals) and Cadwell™ laboratories Spectrum 32 v4.3 signal analyzer and

artificial neural network to aid an anesthesiologist in surgery (column 4, lines 25-50). The current device is used to predict the anesthesia depth of patients based on bolus anesthesia dosage ("Example 1" isoflurane supplemented with intravenous agent midazolam; column 6, lines 56-57), titrated anesthesia dosage (continuous isoflurane vapor during surgery; column 6, lines 58-61), time of wake and sleep (table 1) and corresponding patient dynamics (EEG data acquired during the surgery; column 6, line 62 – column 7, line 9). The EEG of patients is recorded (i.e. device has memory; column 7, lines 3-9) and processed to perform bispectral analysis (BIS) using Fourier Transform (column 7, line 44 – column 8, line 26; Notice: Examiner is interpreting input of ANN to be the signal combiner, hidden layers to be the data processors and output to be the virtual anesthesia monitor; column 7, line 38 - column 8, line 8). The depth of anesthesia during surgery is represented by graphs (fig 2a; column 8, lines 37-64). The system further applies a smoothing function to compensate for sporadic noise in the EEG data (column 8, line 65 - column 9, line 4; Read "Example 1" for detailed description of the data processing).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ATIA SYED whose telephone number is (571)270-7134. The examiner can normally be reached on Monday through Friday, 9:00-5:00 pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ATIA SYED/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769

May 19, 2010